Notices of Final Rulemaking

NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

1. Sections Affected

R4-23-406

Rulemaking Action

Repeal

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rule is implementing (specific):

Authorizing statute: A.R.S. § 32-1904(A)(1) Implementing statute: A.R.S. § 32-1904(A)(1)

3. The effective date of the rule:

March 6, 2004

4. A list of all previous notices appearing in the Register addressing the final rule:

Notice of Rulemaking Docket Opening: 9 A.A.R. 3832, August 29, 2003

Notice of Proposed Rulemaking: 9 A.A.R. 4116, September 26, 2003

5. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy

4425 W. Olive, Suite 140 Glendale, AZ 85302

Telephone: (623) 463-2727, ext. 131

Fax: (623) 934-0583 E-mail: rxcop@cox.net

6. An explanation of the rule, including the agency's reasons for initiating the rule:

Because of statutory changes made to A.R.S. § 32-1963.01 in S.B. 1301 during the 2003 legislative session, R4-23-406 is no longer required. Previous to S.B. 1301, A.R.S. § 32-1963.01(H) required the Board to maintain a list of manufacturers and distributors whose generically equivalent drug could be substituted for the equivalent brand name drug by pharmacists in Arizona. S.B. 1301 removed that list requirement, therefore, subsection (B) of R4-23-406, which describes where that list may be obtained, is no longer necessary. Previous to S.B. 1301, A.R.S. § 32-1963.01(C) required the Board to maintain a list of approved manufacturer's and distributor's abbreviations for use in labeling generically substituted prescriptions. S.B. 1301 removed that list requirement, therefore, subsection (A) of R4-23-406, which describes where that list may be obtained, is no longer necessary. Because the subject matter of R4-23-406 is no longer required by statute, the Board is repealing R4-23-406.

The Board believes that repeal of this rule benefits the public and the pharmacy community by removing a rule that is inconsistent with statute.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

None

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8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

The rulemaking is exempt from writing an economic, small business, and consumer impact statement under A.R.S. § 41-1055(D)(3).

10. A description of the changes between the proposed rule, including supplemental notices, and final rule (if applicable):

There are no changes in the final rule from the proposed rule.

11. A summary of the comments made regarding the rule and the agency response to them:

No comments were received by the Board regarding the rule.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their location in the rule:

None

14. Was this rule previously approved as an emergency rule?

No

15. The full text of the rule follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY ARTICLE 4. PROFESSIONAL PRACTICES

Section

R4-23-406. Substitution for Prescription Drugs Repealed

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-406. Substitution for Prescription Drugs Repealed

- A. Approved abbreviations. If a substitution is made under A.R.S. § 32-1963.01, a pharmacist may use the approved abbreviation that accompanies the name of the manufacturer or distributor listed in subsection (B) of this Section.
- **B.** Manufacturers and distributors. The names of manufacturers and distributors that meet the requirements of A.R.S. § 32-1963.01(H) are recorded and available as a list at the Board office and at www.pharmacy.state.az.us.

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NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

1. Sections Affected Rulemaking Action

R4-23-605 Amend R4-23-607 Amend

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 32-1904(A)(1) and (B)(3)

Implementing statutes: A.R.S. §§ 32-1929, 32-1930, 32-1931, and 32-1933

3. The effective date of the rules:

March 6, 2004

4. A list of all previous notices appearing in the Register addressing the final rules:

Notice of Rulemaking Docket Opening: 9 A.A.R. 3059, July 11, 2003

Notice of Proposed Rulemaking: 9 A.A.R. 4166, October 3, 2003

5. The name and address of agency personnel with whom persons may communicate regarding the rules:

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy

4425 W. Olive, Suite 140 Glendale, AZ 85302

Telephone: (623) 463-2727, ext. 131

Fax: (623) 934-0583 E-mail: rxcop@cox.net

6. An explanation of the rules, including the agency's reasons for initiating the rules:

Because of numerous questions from resident and nonresident drug wholesaler permittees seeking clarification regarding the license and permit verification requirements in R4-23-605(D)(2)(a)(ii) and (iii) and the lack of license and permit verification requirements in R4-23-607(E)(3), the Board decided to amend the nonresident permit rule (R4-23-607) by adding license and permit verification requirements for nonresident permittees like the license and permit verification requirements in place for resident drug wholesaler permittees. While reviewing the verification requirements in R4-23-605, the Board staff noticed that R4-23-605(D)(2)(a)(i) as written could be misinterpreted to mean that a nonprescription drug wholesaler or nonprescription drug retailer is allowed to receive a narcotic or other controlled substance or prescription-only drug or device. Allowing a nonprescription drug wholesaler or nonprescription drug retailer to receive a narcotic or other controlled substance or prescription-only drug or device and the subsection to clarify who may receive a narcotic or other controlled substance or prescription-only drug or device. The proposed rules include format, style, and grammar changes necessary to comply with the current Administrative Procedure Act.

The Board believes the public, resident and nonresident permittees, and the Board benefit from clear, concise, and understandable rules that regulate the receipt and distribution of drugs by resident and nonresident permittees to Arizona citizens

7. A reference to any study relevant to the rules that the agency reviewed and either relied on in its evaluation of or justification for the rules or did not rely on in its evaluation of or justification for the rules, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

None

8. A showing of good cause why the rules are necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

The proposed rules will have minimal economic impact on nonresident wholesalers and manufacturers who ship drugs into Arizona. The proposed rule will require nonresident wholesalers and manufacturers to obtain a copy of the

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license, permit, or registration of the Arizona individual or business to whom a drug is sold. The cost will be minimal, because usually compliance will require only a phone call and the subsequent receipt of a faxed copy of the current license, permit, or registration. Subsequent notice of the need for a copy of a customer's current license, permit, or registration could be done through a note attached to or as part of the customer's invoice. Because the existing rule already requires resident permittees to obtain a copy of a customer's license, permit, or registration, the proposed rules will have no economic impact on resident permittees.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

There are no substantive changes in the final rules from the proposed rules. There are minor changes to style, format, grammar, and punctuation requested by G.R.R.C. staff.

11. A summary of the comments made regarding the rules and the agency response to them:

The Board received one written comment in support of the rules.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their location in the rules:

None

14. Were these rules previously approved as emergency rules?

No

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section

R4-23-605. Resident Drug Wholesaler Permit

R4-23-607. Nonresident Permits

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-605. Resident Drug Wholesaler Permit

- A. Permit. A person shall not operate a business or firm for the wholesale distribution of any drug, device, precursor chemical, or regulated chemical without a current Board-issued <u>full-service</u> or nonprescription drug wholesale permit.
- B. Application.
 - 1. To obtain a permit to operate a <u>full-service</u> or nonprescription drug wholesale firm in Arizona, a person shall submit a completed application on a form furnished by the Board that includes:
 - a. The type of drug wholesale permit;
 - b. Business name, address, mailing address, if different, telephone number, and facsimile number;
 - c. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used:
 - d. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;
 - e. Whether the owner, any officer or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
 - f. Whether the owner, any officer or active partner has ever been denied a drug wholesale permit in this state or any other jurisdiction, and if so, indicate where and when;
 - g. The type of drugs, nonprescription, prescription-only, controlled substances, human, or veterinary, the applicant will distribute;
 - h. Plans or construction drawings showing facility size and security adequate for the proposed business;
 - i. Documentation of compliance with local zoning laws;
 - j. Manager's or responsible person's name, address, emergency telephone number, and resume indicating educational or experiential qualifications related to drug wholesale operation;
 - For an application submitted because of ownership change, the former owner's name and business name, if different;

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- Date signed, applicant's, corporate officer's, partner's, manager's, or responsible person's verified signature and title; and
- m. Fee specified in R4-23-205.
- 2. Before issuing a full service full-service or nonprescription drug wholesale permit, the Board shall:
 - a. Receive and approve a completed permit application;
 - b. Interview the applicant and the responsible person, if different from the applicant, at a Board meeting; and
 - c. Receive a satisfactory compliance inspection report on the facility from a Board compliance officer.
- C. Notification. A <u>full service</u> or nonprescription drug wholesale permittee shall notify the Board of changes involving the type of drugs sold or distributed, ownership, address, telephone number, name of business, manager, or responsible person, including manager's or responsible person's telephone number.
- **D.** Distribution restrictions.
 - 1. Records. A full service or nonprescription drug wholesale permittee shall:
 - a. A full-service drug wholesale permittee shall:
 - <u>i.</u> Maintain records to ensure full accountability of any narcotic or other controlled substance, prescriptiononly drug or device, nonprescription drug, precursor chemical, or regulated chemical including dates of receipt and sales, names, addresses, and DEA registration numbers, if required, of suppliers or sources of merchandise, and customer names, addresses, and DEA registration numbers, if required;
 - b.ii. File the records required in subsection (D)(1)(a)(i) in a readily retrievable manner for a minimum of two years; and
 - e-<u>iii.</u> Make the records required in subsection (D)(1)(a)(<u>i</u>) available upon request during regular business hours for inspection by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4). Records kept at a central location apart from the business location and not electronically retrievable shall be made available within two business days.
 - <u>b.</u> A nonprescription drug wholesale permittee shall:
 - Maintain records to ensure full accountability of any, nonprescription drug, precursor chemical, or regulated chemical including dates of receipt and sales, names, addresses, and DEA registration numbers, if required, of suppliers or sources of merchandise, and customer names, addresses, and DEA registration numbers, if required;
 - ii. File the records required in subsection (D)(1)(b)(i) in a readily retrievable manner for a minimum of two years; and
 - iii. Make the records required in subsection (D)(1)(b)(i) available upon request during regular business hours for inspection by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4). Records kept at a central location apart from the business location and not electronically retrievable shall be made available within two business days.
 - 2. Drug sales.
 - a. A full service full-service drug wholesale permittee shall:
 - i. Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance, <u>or</u> prescription-only drug or device, <u>any nonprescription drug, precursor chemical, or regulated chemical,</u> to anyone except a pharmacy, drug manufacturer, <u>full service or nonprescription or full-service</u> drug wholesaler, <u>or nonprescription drug retailer</u> currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
 - ii. Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone except a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
 - <u>ii-iii.</u>Maintain a copy of the current permit or license of each person or firm who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and
 - iii.iv. Provide permit and license records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).
 - b. A nonprescription drug wholesale permittee shall:
 - i. Not sell or distribute, any nonprescription drug, precursor chemical, or regulated chemical, to anyone except a pharmacy, drug manufacturer, full service full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
 - ii. Maintain a record of the current permit or license of each person or firm who buys, receives, or disposes of any nonprescription drug, precursor chemical, or regulated chemical; and
 - iii. Provide permit and license records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).

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- c. Nothing in this subsection shall be construed to prevent the return of a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical to the original source of supply.
- 3. Out-of-state drug sales.
 - <u>a.</u> A full service full-service drug wholesale permittee shall:
 - <u>a-i.</u> Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, to anyone except a properly permitted, registered, licensed, or certified person or firm of other jurisdictions;
 - b.ii. Maintain a copy of the current permit, registration, license, or certificate of each person or firm who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and
 - e-<u>iii.</u>Provide permit, registration, license, and certificate records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4); and
 - b. A nonprescription drug wholesale permittee shall:
 - i. Not sell or distribute, any nonprescription drug, precursor chemical, or regulated chemical, to anyone except a properly permitted, registered, licensed, or certified person or firm of another jurisdiction;
 - ii. Maintain a record of the current permit, registration, license, or certificate of each person or firm who buys, receives, or disposes of any nonprescription drug, precursor chemical, or regulated chemical; and
 - iii. Provide permit, registration, license, or certificate records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).
- 4. Cash-and-carry sales.
 - A full service or nonprescription <u>full-service</u> drug wholesale permittee shall complete a cash-and-carry sale or distribution of, any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, only after:
 - a.i. Verifying the validity of the order; and
 - b.ii. Verifying the identity of the pick-up person, for each transaction by confirming that the person or firm represented placed the cash-and-carry order: and
 - b. A nonprescription drug wholesale permittee shall complete a cash-and-carry sale or distribution of, any nonprescription drug, precursor chemical, or regulated chemical, only after:
 - i. Verifying the validity of the order; and
 - ii. Verifying the identity of the pick-up person, for each transaction by confirming that the person or firm represented placed the cash-and-carry order.
- **E.** Facility. A full service full-service or nonprescription drug wholesale permittee shall:
 - 1. Ensure that the facility occupied by a <u>full service full-service</u> or nonprescription drug wholesale permittee is of adequate size and construction, well-lighted inside and outside, adequately ventilated, and kept clean, uncluttered, and sanitary:
 - 2. Ensure that the warehouse facility:
 - a. Is secure from unauthorized entry and
 - b. Has an operational security system designed to provide protection against theft and diversion;
 - 3. Ensure In a full-service drug wholesale facility, ensure that only authorized personnel may enter areas where any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is kept;
 - 4. In a nonprescription drug wholesale facility, ensure that only authorized personnel may enter areas where any nonprescription drug, precursor chemical, or regulated chemical is kept;
 - 4.5. Ensure In a full-service drug wholesale facility, ensure that any thermolabile narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is stored in an area where room temperature is maintained in compliance with storage conditions prescribed on the product label;
 - 6. In a nonprescription drug wholesale facility, ensure that any thermolabile nonprescription drug, precursor chemical, or regulated chemical is stored in an area where room temperature is maintained in compliance with storage conditions prescribed on the product label;
 - 5.7. Make the facility available for inspection by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4) during regular business hours-:
 - 6.8. Provide In a full-service drug wholesale facility, provide a quarantine area for storage of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical that is outdated, damaged, deteriorated, misbranded, adulterated, or that is in an open container—; and
 - 9. In a nonprescription drug wholesale facility, provide a quarantine area for storage of any nonprescription drug, precursor chemical, or regulated chemical that is outdated, damaged, deteriorated, misbranded, adulterated, or that is in an open container.

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- F. Quality controls. A full service or nonprescription drug wholesale permittee shall:
 - 1. A full-service drug wholesale permittee shall:
 - a. Ensure that any fire, flood, or otherwise damaged or deteriorated narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is not sold, distributed, or delivered to any person for human or animal consumption;
 - 2.b. Ensure that a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is not manufactured, packaged, repackaged, labeled, or relabeled by any of its employees;
 - 3.c. Ensure that any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical stocked, sold, offered for sale, or delivered is:
 - a.i. Kept clean;
 - b.ii. Protected from contamination and other deteriorating environmental factors; and
 - e-iii. In compliance with applicable federal and state law and official compendium storage requirements;
 - 4.d. Maintain manual or automatic temperature and humidity recording devices or logs to document conditions in areas where any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is stored; and
 - 5.e. Develop and implement a program to ensure that:
 - a.i. Any expiration-dated narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is reviewed regularly;
 - b.ii. Any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, that has less than 120 days remaining on the expiration date, is deteriorated, damaged, or does not comply with federal law, is moved to a quarantine area and not sold or distributed; and
 - e.iii. Any quarantined narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to its source of supply.
 - 2. A nonprescription drug wholesale permittee shall:
 - a. Ensure that any fire, flood, or otherwise damaged or deteriorated nonprescription drug, precursor chemical, or regulated chemical is not sold, distributed, or delivered to any person for human or animal consumption;
 - b. Ensure that a nonprescription drug, precursor chemical, or regulated chemical is not manufactured, packaged, repackaged, labeled, or relabeled by any of its employees;
 - Ensure that any nonprescription drug, precursor chemical, or regulated chemical stocked, sold, offered for sale, or delivered is:
 - Kept clean;
 - ii. Protected from contamination and other deteriorating environmental factors; and
 - iii. In compliance with applicable federal and state law and official compendium storage requirements;
 - d. Maintain manual or automatic temperature and humidity recording devices or logs to document conditions in areas where any nonprescription drug, precursor chemical, or regulated chemical is stored; and
 - e. Develop and implement a program to ensure that:
 - i. Any expiration-dated nonprescription drug, precursor chemical, or regulated chemical is reviewed regularly;
 - ii. Any nonprescription drug, precursor chemical, or regulated chemical, that has less than 120 days remaining on the expiration date, is deteriorated, damaged, or does not comply with federal law, is moved to a quarantine area and not sold or distributed; and
 - iii. Any quarantined nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to its source of supply.

R4-23-607. Nonresident Permits

- **A.** Permit. A person, who is not a resident of Arizona, shall not sell or distribute any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona without:
 - 1. A current Board-issued nonresident pharmacy permit, nonresident manufacturer permit, nonresident full-service or nonprescription drug wholesale permit, or nonresident nonprescription drug permit; and
 - 2. A current equivalent license or permit issued by the licensing authority in the jurisdiction where the person or firm resides.
- **B.** Application. To obtain a nonresident pharmacy, nonresident manufacturer, nonresident full-service or nonprescription drug wholesale, or nonprescription drug permit, a person shall submit a completed application, on a form furnished by the Board, that includes:
 - 1. Business name, address, mailing address, if different, telephone number, and facsimile number;
 - 2. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;
 - 3. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;

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- 4. Whether the owner, any officer, or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
- 5. A copy of the applicant's current equivalent license or permit, issued by the licensing authority in the jurisdiction where the person or firm resides and required by subsection (A)(2);
- 6. For an application submitted because of ownership change, the former owner's name and business name, if different;
- 7. Date signed, applicant's, corporate officer's, partner's, manager's, administrator's, pharmacist-in-charge's, or responsible person's verified signature and title, and
- 8. Fee specified in R4-23-205.
- **C.** In addition to the requirements of subsection (B), the following information is required:
 - 1. Nonresident pharmacy.
 - a. The type of pharmacy;
 - b. Whether the owner, any officer, or active partner has ever been denied a pharmacy permit in this state or any other jurisdiction, and if so, indicate where and when;
 - c. If applying for a hospital pharmacy permit, the number of beds, manager's or administrator's name, and a copy of the hospital's current equivalent license or permit issued by the licensing authority in the jurisdiction where the person or firm resides;
 - d. Pharmacist-in-charge's name and telephone number; and
 - e. For an application submitted because of ownership change, the former pharmacy's name, address, and permit number: and
 - 2. Nonresident manufacturer.
 - a. Whether the owner, any officer, or active partner has ever been denied a drug manufacturer permit in this state or any other jurisdiction, and if so, indicate where and when;
 - b. A copy of the drug list required by the FDA;
 - c. Manager's or responsible person's name, address, and emergency telephone number; and
 - d. The firm's current FDA drug manufacturer or repackager registration number and expiration date; and
 - 3. Nonresident full-service or nonprescription drug wholesaler.
 - a. The type of drug wholesale permit;
 - b. Whether the owner, any officer, or active partner has ever been denied a drug wholesale permit in this state or any other jurisdiction, and if so, indicate where and when;
 - c. The types of drugs, nonprescription, prescription-only, controlled substances, human, or veterinary, the applicant will distribute;
 - d. Manager's or responsible person's name, address, emergency telephone number, and resume indicating educational or experiential qualifications related to drug wholesale operation; and
 - 4. Nonresident nonprescription drug retailer.
 - a. Whether applying for Category I or Category II permit;
 - b. Date business started or planned opening date; and
 - c. Type of business, such as convenience, drug, grocery, or health food store, swap-meet vendor, or vending machine.

D. Notification.

- 1. Nonresident pharmacy. A nonresident pharmacy permittee shall notify the Board of changes involving the type of pharmacy operated, ownership, address, telephone number, name of business, or pharmacist-in-charge.
- 2. Nonresident manufacturer. A nonresident manufacturer permittee shall notify the Board of changes involving listed drugs, ownership, address, telephone number, name of business, or manager, including manager's telephone number.
- 3. Nonresident drug wholesaler. A nonresident full-service or nonprescription drug wholesale permittee shall notify the Board of changes involving the types of drugs sold or distributed, ownership, address, telephone number, name of business, or manager, including manager's telephone number.
- 4. Nonresident nonprescription drug retailer. A nonresident nonprescription drug permittee shall notify the Board of changes involving permit category, ownership, address, telephone number, name of business, or manager, including manager's telephone number.

E. Drug Sales.

- 1. Nonresident pharmacy. A nonresident pharmacy permittee shall not:
 - a. Sell Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona except:
 - i. A pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board;
 - ii. A medical practitioner currently licensed under A.R.S. Title 32; or
 - iii. An Arizona resident upon receipt of a valid prescription order for the resident; and
 - b. Sell Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except:

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- A pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board;
- ii. A medical practitioner currently licensed under A.R.S. Title 32; or
- iii. An Arizona resident either upon receipt of a valid prescription order for the resident or in the original container packaged and labeled by the manufacturer:
- c. Except for a drug sale that results from the receipt and dispensing of a valid prescription order for an Arizona resident, maintain a copy of the current permit or license of each person or firm in Arizona who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and
- d. Provide permit and license records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).
- 2. Nonresident manufacturer. A nonresident manufacturer permittee shall not:
 - a. Sell Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona except, a pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32; and
 - b. Sell Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except, a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
 - c. Maintain a copy of the current permit or license of each person or firm in Arizona who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and
 - d. Provide permit and license records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).
- 3. Nonresident full-service drug wholesaler. A nonresident full-service drug wholesale permittee shall not:
 - a. Sell Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona except a pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32; and
 - b. Sell Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except, a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
 - c. Maintain a copy of the current permit or license of each person or firm in Arizona who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and
 - d. Provide permit and license records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).
- 4. Nonresident nonprescription drug wholesaler. A nonresident nonprescription drug wholesale permittee shall:
 - <u>a.</u> <u>not Not</u> sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except, a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
 - b. Maintain a copy of the current permit or license of each person or firm in Arizona who buys, receives, or disposes of any nonprescription drug, precursor chemical, or regulated chemical; and
 - c. Provide permit and license records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).
- 5. Nonresident nonprescription drug retailer. A nonresident nonprescription drug permittee shall not:
 - a. Sell, distribute, give away, or dispose of, a nonprescription drug, precursor chemical, or regulated chemical to anyone in Arizona except in the original container packaged and labeled by the manufacturer;
 - b. Package, repackage, label, or relabel any drug, precursor chemical, or regulated chemical; or
 - c. Sell, distribute, give away, or dispose of, any drug, precursor chemical, or regulated chemical to anyone in Arizona that exceeds its expiration date, is contaminated or deteriorated from excessive heat, cold, sunlight, moisture, or other factors, or does not comply with federal law.
- **F.** When selling or distributing any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona, a nonresident pharmacy, nonresident manufacturer, nonresident full-service or nonprescription drug wholesale, or nonprescription drug permittee shall comply with federal law, the permittee's resident state drug law, and this Section.